DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Dr. Bruce Lester
Vice President, Research and Development
SterilMed, Inc.
11400 73rd Ave. North
Minneapolis, Minnesota 55369

Re: K012578 – Supplemental Validation Submission
Trade/Device Name: Reprocessed Laparoscope General and Plastic Surgery
(See enclosed list)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: NLM
Dated: August 7, 2001
Received: August 9, 2001

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on November 7, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Reprocessed Laparoscope General and Plastic Surgery (Trocar) Models found to be Substantially Equivalent:

1. Ethicon, 355RT
2. Ethicon, 35LRT
3. Ethicon, 35LRL
4. Ethicon, 511RT
5. Ethicon, 511RL
6. Ethicon, 512RT
7. Ethicon, 512RL

Indications for Use

510(k) Number (if known): K012578

Device Name: Reprocessed Endoscopic Trocars

Indications For Use:

The reprocessed endoscopic trocars are intended to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecological or other minimally invasive surgical procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K012578

NOV 0 7 2001

K012578

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

Contact Person:
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SterilMed, Inc.
11400 73rd Avenue North
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Ph: 763-488-3400
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Date Prepared: August 7, 2001

Trade Name:

Classification Name and Number: Trocar and Cannula
Class II, 21 CFR 876.1500

Product Code: GCJ

Predicate Device(s): The reprocessed endoscopic trocar is substantially equivalent to the Endopath EP Disposable Surgical Trocar (K922608), manufactured by Ethicon; AutoSuture Surgiport® Endoscopic Trocar (K925860), manufactured by US Surgical; and the counterpart devices from the original manufacturer.

Device Description: Reprocessed endoscopic trocars are devices that provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures such as observation, dissecting, cutting, repairing, and removal or manipulation of internal tissues and/or organs. Reprocessed endoscopic trocars are of varying lengths and diameters, and may have either a blunt or bladed obturator tip.

Intended Use: This device is designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures.

Functional and Safety Testing:

Representative samples of reprocessed endoscopic trocars underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The reprocessed endoscopictrocars are substantially equivalent to the Endopath EP Disposable surgical Trocar (K922608), manufactured by Ethicon; AutoSuture Surgiport® Endoscopic Trocar (K925860), manufactured by US Surgical; and the counterpart devices from the original manufacturer. This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.